

|   |   |    |   |                          |                    |
|---|---|----|---|--------------------------|--------------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |                    |
|   |   |    |   | Application Number       | 10/578,077         |
|   |   |    |   | Filing Date              | May 8, 2007        |
|   |   |    |   | First Named Inventor     | Yoshio MIKI et al. |
|   |   |    |   | Art Unit                 | 1634               |
|   |   |    |   | Examiner Name            | Diana B. JOHANNSEN |
| Sheet   | 1 | of | 1 | Attorney Docket Number   | 08178.0031-00000   |

| U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS |                       |  |   |   |   |
|---|-----------------------|--|---|---|---|
| Examiner Initials                                   | Cite No. <sup>1</sup> | Document Number                          | Issue or Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|   |                       | Number-Kind Code <sup>2</sup> (if known) |   |   |   |
|   |                       |  |   |   |   |

**Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.**

| FOREIGN PATENT DOCUMENTS |                       |   |                                |   |   |                          |
|--------------------------|-----------------------|---|--------------------------------|---|---|--------------------------|
| Examiner Initials        | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document           | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation <sup>6</sup> |
|                          |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) |                                |   |   |                          |
|                          |                       | JP 2003-93068   | 04-02-2003                     | Director General of National Institute of Health Sciences |   | Abstract only            |

| NONPATENT LITERATURE DOCUMENTS |                       |   |                          |
|--------------------------------|-----------------------|---|--------------------------|
| Examiner Initials              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation <sup>6</sup> |
|                                |                       | BAHADUR et al., "CYP2C8 polymorphisms in Caucasians and their relationship with paclitaxel 6α-hydroxylase activity in human liver microsomes," <i>Biochemical Pharmacology</i> , 64: 1579-1589 (2002).  |                          |
|                                |                       | CAHILL et al., "Mutations of mitotic checkpoint genes in human cancers," <i>Nature</i> , 392: 300-303 (1998).   |                          |
|                                |                       | DAI, et al., "Polymorphisms in human CYP2C8 decrease metabolism of the anticancer drug paclitaxel and arachidonic acid," <i>Pharmacogenetics</i> , 11:597-607 (2001).   |                          |
|                                |                       | HOYT et al., "S. cerevisiae genes required for cell cycle arrest in response to loss of microtubule function," <i>Cell</i> , 66:507-517 (1991).   |                          |
|                                |                       | LI et al. "Feedback control of mitosis in budding yeast," <i>Cell</i> , 66:519-531 (1991).  |                          |
|                                |                       | NAKAJIMA et al., "Genetic polymorphisms of CYP2C8 in Japanese population," <i>Drug Metabolism and Disposition</i> , 31(6):687-690 (2003).   |                          |
|                                |                       | RAHMAN et al., "Selective biotransformation of taxol to 6α-hydroxytaxol by human cytochrome P450 2C8," <i>Cancer Research</i> , 54:5543-5546 (1994).  |                          |
|                                |                       | RELLING et al., "Pharmacogenetics and cancer therapy," <i>Nature Reviews -Cancer</i> , 1:99-108 (2001).   |                          |
|                                |                       | SOYAMA, "Non-synonymous single nucleotide alterations found in the CYP2C8 gene result in reduced <i>in vitro</i> paclitaxel metabolism," <i>Biol. Pharm. Bull.</i> , 24(12): 1427-1430 (2001).  |                          |
|                                |                       | SOYAMA et al., "Five novel single nucleotide polymorphisms in the CYP2C8 gene, one of which induces a frame-shift," <i>Drug Metabol. Pharmacokin.</i> 17(4):SNP7 (374)-(SNP10) 377 (2002).  |                          |
|                                |                       | JSNP DATABASE ( <a href="http://snp.ims.u-tokyo.ac.jp/">http://snp.ims.u-tokyo.ac.jp/</a> ), JSNP ID: IMS-JST111898 (October 11, 2001)  |                          |
|                                |                       | International Search Report for International Application No. PCT/JP2004/016805, dated February 1, 2005.  | Yes                      |
|                                |                       | PCT International Preliminary Report on Patentability and Written Opinion of the International Searching Authority for International Application No. PCT/JP2004/016805, dated July 27, 2006.  | Yes                      |

|                    |                      |                 |            |
|--------------------|----------------------|-----------------|------------|
| Examiner Signature | /Diana B. Johannsen/ | Date Considered | 02/13/2010 |
|--------------------|----------------------|-----------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.B.J.